

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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In re K-DUR ANTITRUST LITIGATION	)	Civil Action No. 01-1652 (JAG)
	)	MDL Docket No. 1419
	)	
	)	
This document is applicable to ALL	)	
ACTIONS	)	
	)	

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**DEFENDANTS' BRIEF IN RESPONSE  
TO NON-CLASS PHARMACY PLAINTIFFS'  
AND DIRECT PURCHASER CLASS PLAINTIFFS' RULE 16  
REQUEST FOR STATUS CONFERENCE**

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Defendants Schering-Plough Corporation, Key Pharmaceuticals, Inc. (collectively "Schering"), Upsher-Smith Laboratories, Inc. ("Upsher-Smith"), Wyeth and ESI Lederle submit this response to the Non-Class Pharmacy Plaintiffs' and Direct Purchaser Class Plaintiffs' Rule 16 Request for a Status Conference ("Rule 16 Request"). For the reasons described more fully below, defendants respectfully suggest that a status conference to discuss scheduling would be premature until the Court has had the opportunity to rule on defendants' pending motions on the pleadings.

Plaintiffs claim that a status conference is necessary "to put in place a schedule for the completion of discovery in this case and the setting of operative deadlines." (Rule 16 Request at 1). Defendants have fully complied with their discovery obligations to date, producing hundreds of thousands of pages of documents and testimony from the underlying FTC Action. Plaintiffs are putting the cart before the horse, however, in suggesting that the Court address the scheduling of additional discovery and other matters before it decides defendants' pending Rule 12 motions.

As defendants recently noted in response to plaintiff Louisiana Wholesale Drug Company's motion to amend its complaint, defendants' Rule 12 motions challenge the sufficiency of *all* plaintiffs' claims. Defendants' motions rest primarily on the ground that plaintiffs have failed to allege that the settlements of the Upsher-Smith and ESI patent cases extended Schering's rights beyond the reasonable scope of the '743 patent. (Defendants' Response To Plaintiff Louisiana Wholesale Drug Company's Motion For Leave To Amend To File Amended Class Action Complaint at 5). If the Court grants defendants' motions, all plaintiffs – including the Non-Class Pharmacy Plaintiffs and the Direct Purchaser Class Plaintiffs – who wish to pursue their claims will be required to

seek leave to amend their complaints, if possible, to address the merits of the Upsher-Smith and ESI patent litigations. Defendants respectfully suggest that it makes little sense for the parties and this Court to attempt to set a schedule for additional discovery and other proceedings in this case without first knowing whether these significant amendments to plaintiffs' complaints will be required.<sup>1</sup>

Defendants also dispute plaintiffs' characterization that a scheduling conference is warranted because defendants have delayed discovery or because the case "remains at a complete standstill." (Rule 16 Request at 2). Plaintiffs are well aware that defendants have more than complied with all of this Court's and Magistrate Judge Haneke's Orders regarding discovery. Indeed, defendants have produced, either pursuant to those Orders or *voluntarily*, hundreds of thousands of pages of documents to plaintiffs.

Schering, for example, has produced the following discovery in this action pursuant to Court Order:

1. approximately 60,000 pages of documents from the underlying patent litigations;
2. the settlement and license agreements from the underlying patent litigations;
3. Schering's privilege log produced to the FTC in the FTC Action;
4. transcripts of depositions of all Schering witnesses taken in the FTC Action;
5. documents Schering identified and used as trial exhibits in the FTC Action; and

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<sup>1</sup> The scope of future proceedings on class and merits issues may also be significantly affected by the Court's ruling on defendants' motions to dismiss plaintiffs' state law claims.

6. the 225,000+ pages Schering produced to the FTC in the FTC Action, including Complaint Counsel's First and Second Requests for Production of Documents and Things Issued to Schering-Plough.

In addition, Schering has *voluntarily* produced additional documents consisting of electronic sales data, sales contracts and pricing information for its K-Dur 20 product and the generic equivalent to K-Dur 20 marketed by Schering subsidiary Warrick Pharmaceuticals.

Similarly, Upsher-Smith has produced, either voluntarily or pursuant to Court Orders, the following documents to plaintiffs:

1. all documents Upsher-Smith produced to the FTC in the FTC Action;
2. Complaint Counsel's document requests in the FTC Action and Upsher-Smith's responses to those requests;
3. an index of Upsher-Smith's production to the FTC;
4. Upsher-Smith's privilege log from the FTC Action;
5. a list of all Upsher-Smith individuals whose files were searched in connection with Upsher-Smith's production in the FTC Action;
6. data, in paper and electronic formats, regarding Upsher-Smith's potassium sales from September 2001 through the first quarter of 2003.

Wyeth has likewise made a comprehensive production to plaintiffs, providing documents including:

1. its privilege log from the FTC Action;
2. all documents it produced to the FTC in the FTC Action;
3. copies of depositions of Wyeth witnesses taken in the FTC Action;
4. copies of the public versions of the hearing transcript from the FTC Action.

As plaintiffs acknowledge (Rule 16 Request at 2), they raised these same concerns regarding discovery with Magistrate Judge Haneke in June 2003, when they made a request similar to the instant request for a status conference. Defendants responded by submitting letters to Magistrate Judge Haneke that described in detail all the discovery defendants had provided to date. Magistrate Judge Haneke did not schedule a status conference or order any additional discovery.

Plaintiffs cannot point to any development in this case that would suggest that the Court should revisit the issues raised before Magistrate Judge Haneke. Defendants have more than complied with their discovery obligations, and the case has made steady progress while the Court has considered defendants' Rule 12 motions. Plaintiffs' request for a conference "to set a schedule for the completion of this case" (Rule 16 Request at 2) is premature given the current procedural posture of the case. Defendants respectfully submit that the interests of judicial economy will be best served if the parties and the Court determine an appropriate schedule of further proceedings *after* the Court has issued its decisions on the Rule 12 motions that will define the scope of those further proceedings.<sup>2</sup>

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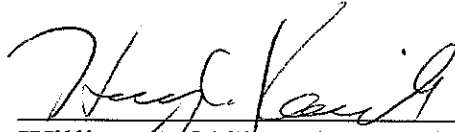
<sup>2</sup> The Commission's recent decision in the FTC Action does not change this analysis at all. First, the Commission's decision does not bind this Court in any way, and it certainly does not effect this Court's discretion to manage this multidistrict litigation. Furthermore, Schering and Upsher-Smith have each filed petitions for review of the Commission's decision in the United States Court of Appeals for the Eleventh Circuit. Defendants fully expect the Eleventh Circuit to determine that the Commission's order cannot stand because, *inter alia*, the Commission failed to take the merits of the underlying patent litigations and the scope of Schering's patent properly into account when evaluating the reasonableness of the patent settlement agreements. *See, e.g., Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1305 (11<sup>th</sup> Cir. 2003) (reversing per se condemnation of patent settlement, even where brand-name drug patent subsequently held invalid, because the effect on production of generic drug's

## CONCLUSION

For the foregoing reasons, defendants submit that plaintiffs' request for a Rule 16 conference to discuss a schedule for the completion of discovery and other pretrial proceedings is premature and should be denied.<sup>3</sup>

Respectfully submitted,

Dated: February 23, 2004

  
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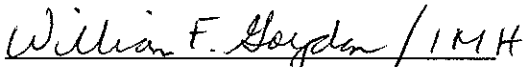
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production "appear[ed] to be no broader than the potential exclusionary effect of the '207 patent, and was actually narrower to the extent it permitted [generic] to market its drug before the '207 patent expired").

<sup>3</sup> In a letter dated February 13, 2004, counsel for the Indirect Purchaser Plaintiffs requested a status conference with Magistrate Judge Haneke to "address the current hiatus in these proceedings awaiting Judge Greenaway's decision on the motions to dismiss, as well as various discovery issues." (*See* 2/13/04 Letter from Allyn Z. Lite to Magistrate Judge Haneke at 1, attached as Exhibit 1). To the extent that the Indirect Purchaser Plaintiffs are requesting a conference to address scheduling issues, such a conference would be premature for the reasons stated above. To the extent that the Indirect Purchaser Plaintiffs are asking Magistrate Judge Haneke to revisit previous decisions regarding the appropriate scope of discovery, defendants respectfully submit that the Indirect Purchaser Plaintiffs still have not provided – and could not provide at a status conference – any grounds to justify their requests that defendants be required to produce at this time "all trial exhibits, expert reports, *in camera* transcripts and unredacted versions of both the Administrative Law Judge's decision and the FTC opinion." (*Id.*).

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# EXHIBIT 1

Feb-13-04 02:23pm From-

T-690 P.002/005 F-030

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February 13, 2004

**Via Hand Delivery**

Honorable G. Donald Haneke, U.S.M.J.  
United States District Court  
M.L. King, Jr. Federal Building  
& United States Courthouse  
50 Walnut Street  
Newark, New Jersey 07101

Re: **In re K-Dur Antitrust Litigation**  
Civil Action No. 01-1652 (JAG)  
(Consolidated Cases)  
MDL Docket No. 1419

Dear Judge Haneke:

I am court appointed liaison counsel for plaintiffs in the above captioned consolidated actions. I write on behalf of the indirect purchaser plaintiffs to request a case management conference with the Court to address the current hiatus in these proceedings awaiting Judge Greenaway's decision on the motions to dismiss, as well as various discovery issues. On December 18, 2003 plaintiffs forwarded to Judge Greenaway a copy of the FTC opinion reversing the Initial Decision of the Administrative Law Judge in In re Schering-Plough Corporation, et al., Docket No.: 19297.

In light of the FTC opinion, plaintiffs would like to revisit with Your Honor various discovery related matters previously identified to the Court, including defendants' obligations to produce various documents already produced by defendants to the FTC. While many of these documents have been produced and reviewed, we would like to address, among other things, production of all of the trial exhibits, expert reports, *in camera* transcripts and unredacted versions of both the Administrative Law Judge's decision and the FTC opinion.

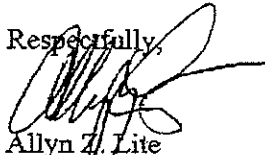
Feb-13-04 02:23pm From-

T-690 P.003/005 F-030

Hon. G. Donald Haneke, U.S.M.J.  
February 13, 2004  
Page 2

We appreciate Your Honor's assistance in this matter and look forward to a conference at the earliest possible time in the Court's schedule.

Respectfully,



Allyn Z. Lite

AZL:KB:emp

cc: Honorable Joseph A. Greenaway, Jr.  
Defense Counsel (on attached list)  
Plaintiffs Co-Lead Counsel (on attached list)

Feb-13-04 02:23pm From-

T-890 P.004/005 F-030

**In re K-DUR ANTITRUST LITIGATION MDL**  
**Docket No. 1419 (JAG)**

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Feb-13-04 02:24pm From-

T-690 P.005/005 F-030

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